

CLAIMS

What is claimed is:

1. A process for coating a pharmaceutical particle with a liquid, the process comprising the steps of:

- (a) metering a coating liquid into a flow restrictor;
- (b) injecting a gas stream through the flow restrictor concurrently with step (a) to (i) atomize the coating liquid and (ii) create turbulent flow of the gas stream, wherein the gas stream is optionally heated; and
- (c) adding a pharmaceutical particle to the turbulent flow region concurrently with steps (a) and (b) wherein the pharmaceutical particle mixes with the atomized coating liquid in the region of turbulent flow, to provide a coated pharmaceutical particle.

2. The process of Claim 1, wherein the pharmaceutical particle is selected from the group consisting of vitamins, supplements, minerals, enzymes, proteins, peptides, antibodies, vaccines, probiotics, bronchodilators, anabolic steroids, analeptics, analgesics, anesthetics, antacids, antihelmintics, anti-arrhythmics, antibiotics, anticoagulants, anticolonergics, anticonvulsants, antidepressants, antidiabetics, antidiarrheals, anti-emetics, anti-epileptics, antihistamines, antihormones, antihypertensives, anti-inflammatories, antimuscarinics, antimycotics, antineoplastics, anti-obesity drugs, antiprotozoals, antipsychotics, antispasmodics, anti-thrombics, antithyroid drugs, antitussives, antivirals, anxiolytics, astringents, beta-adrenergic receptor blocking drugs, bile acids, bronchospasmolytic drugs, calcium channel blockers, cardiac glycosides, contraceptives, corticosteroids, diagnostics, digestives, diuretics, dopaminergics, electrolytes, emetics, haemostatic drugs, hormones, hormone replacement therapy drugs, hypnotics, hypoglycemic drugs, immunosuppressants, impotence drugs, laxatives, lipid regulators, muscle relaxants, pain relievers, parasympathicolytics, parasympathomimetics, prostaglandins, psychostimulants, sedatives, sex steroids, spasmolytics, sulfonamides, sympathicolytics, sympathicomimetics, sympathomimetics, thyromimetics, thyreostatic drugs, vasodilators, and xanthines or combinations thereof.

3. The process of Claim 1, wherein the liquid coating material comprises a starch, gelatin, a natural color, a synthetic color, a sugar, a cellulose, a biodegradable polymer, a biodegradable oligomer, an

emulsifying wax, a fat, a wax, a phospholipid, a shellac, a flavoring agent, a moisture barrier, a taste-masking agent, an odor-masking agent, a shelf-life extending agent, a lipid, a protein, a mineral, cellulose derivatives, alginate, chitosan, surfactants and other wetting agents, carbohydrates, natural or synthetic polymers, methacrylate polymers and copolymers, polylactic acid (PLA) and poly lactide co-glyceride (PLGA), ethyl cellulose, methyl cellulose, hydroxypropyl cellulose, polyvinylpyrrolidone, Aquateric™ Eudragit™, including any commercial grade or formulations thereof, acrylic coatings, Surelease™, bubble gum flavor, cherry flavor, grape flavor, sodium lauryl sulfate, sodium docusate, polysorbate, polyoxyethylene alkyl ethers, Cremophor, polyoxyethylene stearates, sorbitan fatty acid ester, Tween, poly lactic acid, poly lactide glycolic acid, cellulose acetate phthalate, lactose, fructose, trehalose, microcrystalline cellulose, mannitol, dicalcium phosphate, dextrates, croscarmellose sodium, sodium starch glycolate, povidone, silicon dioxide, stearic acid, a hydrocolloid, a monosaccharide, a disaccharide, an oligosaccharide, a polysaccharide, a surface modifying agent, a sugar alcohol, a poly-ol, a flow aid, an interparticle force control agent, magnesium stearate, talc, a pharmaceutically - active liquid, and combinations thereof.

4. The process of Claim 1, further comprising repeating steps (a)-(c) at least once wherein the liquid coating material is the same or different.

5. A coated pharmaceutical particle made by the process of Claim 1.

6. A process for coating a pharmaceutical particle with a liquid, the process comprising the steps of:

- (a) metering a coating liquid containing pharmaceutical particles into a flow restrictor;
- (b) injecting a gas stream through the flow restrictor concurrently with step (a) to (i) atomize the coating liquid and (ii) create turbulent flow of the gas stream and the atomized coating liquid, wherein the gas stream is optionally heated;

wherein the pharmaceutical particle mixes with the atomized coating liquid in the region of turbulent flow, to provide a coated pharmaceutical particle.

7. The process of Claim 6, wherein the pharmaceutical particle is selected from the group consisting of vitamins, supplements, minerals,

enzymes, proteins, peptides, antibodies, vaccines, probiotics, bronchodilators, anabolic steroids, analeptics, analgesics, anesthetics, antacids, antihelmintics, anti-arrhythmics, antibiotics, anticoagulants, anticolenergics, anticonvulsants, antidepressants, antidiabetics, antidiarrheals, anti-emetics, anti-epileptics, antihistamines, antihormones, antihypertensives, anti-inflammatories, antimuscarinics, antimycotics, antineoplastics, anti-obesity drugs, antiprotozoals, antipsychotics, antispasmodics, anti-thrombics, antithyroid drugs, antitussives, antivirals, anxiolytics, astringents, beta-adrenergic receptor blocking drugs, bile acids, bronchospasmolytic drugs, calcium channel blockers, cardiac glycosides, contraceptives, corticosteroids, diagnostics, digestives, diuretics, dopaminergics, electrolytes, emetics, haemostatic drugs, hormones, hormone replacement therapy drugs, hypnotics, hypoglycemic drugs, immunosuppressants, impotence drugs, laxatives, lipid regulators, muscle relaxants, pain relievers, parasympatholytics, parasympathomimetics, prostaglandins, psychostimulants, sedatives, sex steroids, spasmolytics, sulfonamides, sympatholytics, sympathicomimetics, sympathomimetics, thyromimetics, thyreostatic drugs, vasodilators, and xanthines or combinations thereof.

8. The process of Claim 6, wherein the liquid coating material comprises a starch, gelatin, a natural color, a synthetic color, a sugar, a cellulose, a biodegradable polymer, a biodegradable oligomer, an emulsifying wax, a shellac, a flavoring agent, a moisture barrier, a taste-masking agent, an odor-masking agent, a shelf-life extending agent, a lipid, a protein, a mineral, cellulose derivatives, alginate, chitosan, surfactants and other wetting agents, carbohydrates, natural or synthetic polymers, methacrylate polymers and copolymers, polylactic acid (PLA) and poly lactide co-glyceride (PLGA), methyl cellulose, hydroxypropylcellulose, polyvinylpyrrolidone, Aquateric™ (commercial coating), Eudragit™, including any commercial grade or formulations thereof, acrylic coatings, Surelease™, bubble gum flavor, cherry flavor, grape flavor, sodium lauryl sulfate, sodium docosate, polysorbate, polyoxyethylene alkyl ethers, Cremophor, polyoxyethylene stearates, sorbitan fatty acid ester, tween, polylactic acid, polylactide glycolic acid, cellulose acetate phthalate, lactose, microcrystalline cellulose, mannitol, dicalcium phosphate, dextrates, croscarmellose sodium, sodium starch glycolate, povidone, silicon dioxide, stearic acid, a hydrocolloid, a monosaccharide, a disaccharide, an oligosaccharide, a polysaccharide, a

surface modifying agent, a sugar alcohol, a poly-ol, a flow aid, a n interparticle force control agent, magnesium stearate, a pharmaceutically-active liquid, talc, and combinations thereof.

9. The process of Claim 6, further comprising repeating steps (a)-(b) at least once wherein the liquid coating material is the same or different.

10. A coated pharmaceutical particle made by the process of Claim 6.

11. A coated pharmaceutical particle made by the process of Claim 1 or 6 comprising ibuprofen coated with Eudragit® RL30D.

12. A coated pharmaceutical particle made by the process of Claim 1 or 6 comprising ibuprofen coated with ethylcellulose.

13. A pharmaceutical particle made by the process of Claim 1 or 6 wherein the coating the liquid is Poloxamer® 188.

14. A pharmaceutical particle of Claim 13, wherein the particle comprises ibuprofen.

15. A process for coating a carrier particle with a liquid comprising a pharmaceutically active ingredient, the process comprising the steps of:

- (a) metering a coating liquid comprising a pharmaceutically active ingredient into a flow restrictor;
- (b) injecting a gas stream through the flow restrictor concurrently with step (a) to (i) atomize the coating liquid and (ii) create turbulent flow of the gas stream, wherein the gas stream is optionally heated; and
- (c) adding a carrier particle to the turbulent flow region concurrently with steps (a) and (b) wherein the carrier particle mixes with the atomized coating liquid in the region of turbulent flow, to provide a particle coated with a pharmaceutically active ingredient.

16. A process for coating a carrier particle with a liquid comprising a pharmaceutically active ingredient, the process comprising the steps of:

- (a) metering into a flow restrictor a coating liquid comprising a pharmaceutically active ingredient wherein said liquid further comprises carrier particles;
- (b) injecting a gas stream through the flow restrictor concurrently with step (a) to (i) atomize the coating liquid and (ii) create turbulent flow of the gas stream, wherein the gas stream is optionally heated;

wherein the carrier particles mix with the atomized coating liquid in the region of turbulent flow, to provide a particle coated with a pharmaceutically active ingredient.

17. The process of Claims 15 or 16 wherein said carrier particles are comprised of inert material.

18. The process of Claim 17, wherein said carrier particles are selected from the group consisting of silica, titanium dioxide and lactose.

19. Coated particles made by the process of Claims 15 or 16.

20. The process of Claims 15 or 16, wherein the pharmaceutically active ingredient in the liquid comprising a pharmaceutically active ingredient is selected from the group consisting of vitamins, supplements, minerals, enzymes, proteins, peptides, antibodies, vaccines, probiotics, bronchodilators, anabolic steroids, analeptics, analgesics, anesthetics, antacids, antihelmintics, anti-arrhythmics, antibiotics, anticoagulants, anticoloneergics, anticonvulsants, antidepressants, antidiabetics, antidiarrheals, anti-emetics, anti-epileptics, antihistamines, antihormones, antihypertensives, anti-inflammatories, antimuscarinics, antimycotics, antineoplastics, anti-obesity drugs, antiprotozoals, antipsychotics, antispasmodics, anti-thrombics, antithyroid drugs, antitussives, antivirals, anxiolytics, astringents, beta-adrenergic receptor blocking drugs, bile acids, bronchospasmolytic drugs, calcium channel blockers, cardiac glycosides, contraceptives, corticosteroids, diagnostics, digestives, diuretics, dopaminergics, electrolytes, emetics, haemostatic drugs, hormones, hormone replacement therapy drugs, hypnotics, hypoglycemic drugs, immunosuppressants, impotence drugs, laxatives, lipid regulators, muscle relaxants, pain relievers, parasympathicolytics, parasympathicomimetics, prostagladins, psychostimulants, sedatives, sex steroids, spasmolytics, sulfonamides, sympathicolytics, sympathicomimetics, sympathomimetics, thyreomimetics, thyreostatic drugs, vasodialators, and xanthines or combinations thereof.

21. A composition comprised of pharmaceutical particles having a size greater than about 100 nm and less than about 100  $\mu$ m, coated with a surface active agent, wherein said particles exhibit enhanced dissolution.

22. The composition of Claim 21 wherein said the particles are coated with said surface active agent from between 0.1% to about 30% by % weight of the coating material to final weight of the composition of coated particles.

23. The composition of Claim 22, wherein said particles exhibit an enhancement in rate of dissolution of at least 10%.

24. The composition of Claim 23 wherein the particles are about 0.5  $\mu\text{m}$  to about 25  $\mu\text{m}$ , and are coated with surface active agent from  
5 between about 1% to about 20%.

25. The composition of Claim 24, wherein the particles are about 1  $\mu\text{m}$  to about 15  $\mu\text{m}$ , and are coated with surface active agent from  
10 between about 1% to about 10%.

26. The particles of Claim 25, wherein said particles exhibit an enhancement in rate of dissolution of at least 200%.

27. A particle of ibuprofen between 100 nm and 100  $\mu\text{m}$  coated with a surface active agent wherein said particle exhibits an enhanced rate of dissolution.

28. The particle of Claim 27, wherein said surface active agent is  
15 Poloxamer® or SLS.

29. A particle of ibuprofen between 100 nm and 100  $\mu\text{m}$  coated with Poloxamer® wherein said particle exhibits an enhanced rate of dissolution.